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Signed R. Mahoney

Dated 14 September 2000

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Request for grant of a patent

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26 AUG 1999

The Patent Office

Cardiff Road
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1. Your reference

P24394/CPA/RMC

2. Patent application number
(The Patent Office will fill in this part)

9920112.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

AorTech International plc
Phoenix Crescent
Strathclyde Business Park
BELLSHILL
ML4 3NJ
United Kingdom

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

UK 7722249001

4. Title of the invention

Improvements Relating to Catheters (I)

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Murgitroyd & Company
373 Scotland Street
GLASGOW
G5 8QA
United Kingdom

Patents ADP number *(if you know it)*

1198013

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	7
Claim(s)	–
Abstract	–
Drawing(s)	2 ~~2~~ 2

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature "Murgitroyd & Company" Date Murgitroyd & Company 25/8/1999

12. Name and daytime telephone number of person to contact in the United Kingdom: Roisin McNally, 0141 307 8400

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IMPROVEMENTS RELATING TO CATHETERS (I)

The present invention relates to improvements for catheters having a heat transfer device at or near their distal end.

One of the present constraints concerning manufacture of catheters designed to monitor various cardiac output data is the manner and form of the required heat transfer device system. One present form of heat transfer device involves a thermal coil radially disposed about the catheter body to form a generally tubular coil which extends along the outside wall of the catheter. Such a heat transfer device is shown in US 5509424. However, such heat transfer coils require time and effort to wind and form and also restrict the possible miniaturisation of such catheters for use in paediatrics.

It is an object of the present invention to provide improvements to the manner and nature of heat transfer devices for use with catheters.

Thus, according to one aspect of the present invention, there is provided a catheter having a heat transfer

device at or near its distal end, the heat transfer device being a flexible film having one or more electrical resistor flow paths thereon or therethrough, which film is locatable around the catheter wall.

Such films can include flexible metal films on which one or more electrical paths have been etched or otherwise created. Alternatively, one or more electrical paths could be added onto a plastic film backing. The form of addition includes any type of deposition or coating, and the one or more electrical paths could be formed by etching, etc to form the resistor structure.

One or more temperature sensors or sensor leads could be included on or within the heat transfer device film to monitor the temperature of the electrical path(s), and thus the temperature of the overall heat transfer device.

Suitable plastic backing materials include PVC, polyurethane, silk, etc, possibly about 20-80 microns thick, and suitable thin high resistant metal films include nickel, chromium or nickel-chromium. These can be deposited on the plastic backing material, and pattened using a photolithography mask to form the resistor structure.

~~On top of the resistor structure could be located a~~ suitable insulator like parylene C, followed by deposition of a suitable temperature sensing means e.g. thermistors or platinum. Finally the outer surface may be coated with a silver or gold layer, possibly 5-10 microns thick. Optionally a further layer of parlyene C is added as the outer layer.

According to a third aspect of the present invention, there is provided a catheter having a heat transfer device at or near its distal end, wherein the heat transfer device is disposed onto the catheter wall by any known method of deposition, eg plasma deposition, printing, etc. Application by printing, uses eg conductive ink, or a conductive layer, with subsequently etching. This method of deposition can be use any suitable resistive material, in addition, the sensor material could be similarly applied.

Possible arrangements for the electrical paths and temperature sensing means across the backing material are shown in Figures 3 and 4 of the accompanying drawings.

This form of heat transfer device can be fixed around a catheter at or near its distal end. Preferably the film is still about 0.5-2.0 cm long, in order for it to remain within the main pulmonary artery trunk. The film could be fixed around the catheter starting at about 4-5 cm from the tip, and in the case of a PVC catheter body, the PVC film heat transfer device could be bonded by solvent.

Such a heat transfer device could be adapted to fit a 3-5F catheter. The heat transfer device should not increase the outer diameter of the catheter more than about 0.3F

Using the same technique, a similar film could be formed purely for temperature sensing. The temperature sensing material could be deposited on a backing film, followed by parylene (and gold) coatings. Such a temperature sensor could be positioned to 2-4 cm proximal to the heat transfer device. Optionally a

further layer of parlyene C is added as the outer layer.

According to a second aspect of the present invention, there is provided a catheter having a length of its outer wall formed wholly, substantially or partly from doped material able to act as a heat transfer device upon application of power therethrough.

This form of heat transfer device could be formed as an inherent part of the catheter wall, rather than as a separate addition of a heat transfer device to the catheter. The catheter wall is sufficiently doped with a resistive material or ingredient able to pass electrical current therethrough, without affecting its other properties. Any conductive material could be suitable, eg silver, gold.

According to a third aspect of the present invention, there is provided a catheter having a heat transfer device at or near its distal end, wherein the heat transfer device is disposed onto the catheter wall by any known method of deposition, eg plasma deposition, printing, etc. Application by printing uses eg conductive ink, or a conductive layer, with subsequently etching. This method of deposition can be use any suitable resistive material. In addition, the temperature sensor material could be similarly applied.

According to a fourth aspect of the present invention, there is provided a catheter wall having one or more metal wires therethrough.

By locating the electrical connections within the catheter wall body, separate lumens for electrical connections to its distal end within the catheter

interior are no longer required.

The wire(s) can be formed from any suitable metal, eg copper. Preferably, each wire is co-extruded within the catheter body.

More preferably, there are one or more sets of electrical wires in the catheter wall, each set having the required number of wires for the desired operations.

In one embodiment of the present invention, the catheter body has three sets of wires, each set comprising two wires. One set of wires is for a heating element, and the other two sets are for each of two temperature sensing elements located on or along the catheter wall.

The wire or wires inside the catheter wall should be easily exposable and thus connectable to the required electrical units to which they correspond. Any exposed wire could be covered by a suitable insulator such as vinyl adhesive, and urethane potting compound.

An example of this aspect of the present invention is shown in Figure 2 of the accompanying drawings.

According to a fifth aspect of the present invention, there is provided a catheter combining the first and third aspects described above.

One advantage of the use of one or more aspects of the present invention as described above is the ability to reduce the size of the catheter, more particularly for paediatric use. A catheter wherein the electrical wires required for the heat transfer device, etc are

co-extruded within the catheter body, means that the catheter may only need a single distal lumen, (possibly 0.5-0.7 mm diameter) for solution infusion and pressure monitoring.

The novel apparatus and methods of the present invention could also be used in non-medical fields using heat transfer devices at or near the distal ends of elongate tubing to be located in remote locations. Such fields include aeronautics, any fluid flow analysis, food and drink processing and monitoring, water and sewerage management, chemical engineering, fuel supply to engines, etc.

The present invention is also particularly applicable to the paediatric catheter field.

Embodiments of the present invention are shown by way of example only in the accompanying diagrammatic drawings in which:

Figure 1 is a side view of a paediatric catheter;

Figure 2 is a cross-sectional view of a catheter wall having electrical wires located therein;

Figures 3 and 4 are examples of a heat transfer device film for application around a catheter body;

Figure 5 is a cross-sectional view of a catheter body having a heat transfer device there around according to Figure 3;

Figures 6a, b and c show an alternative method of forming the distal end of a catheter having a heat transfer device, wherein the heat transfer device can

be fabricated by using a piece of catheter tubing, and then applying the deposition directly on the catheter tube. The heat transfer device tube is then bonded to the catheter body.

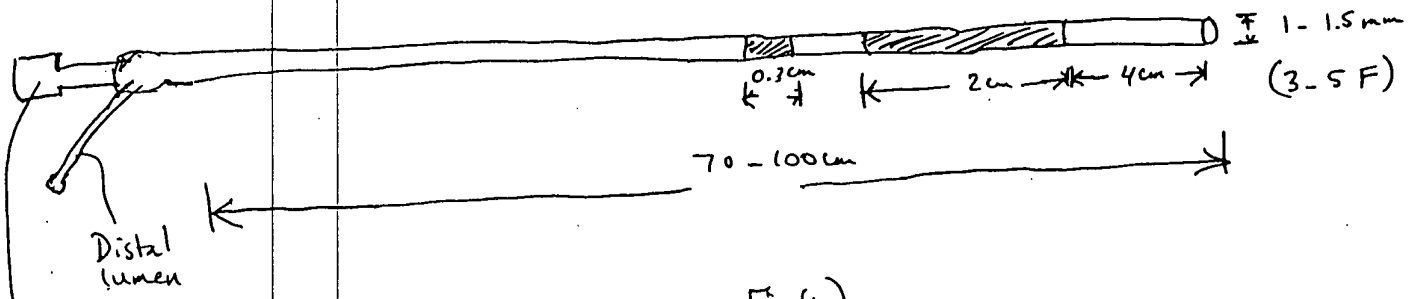
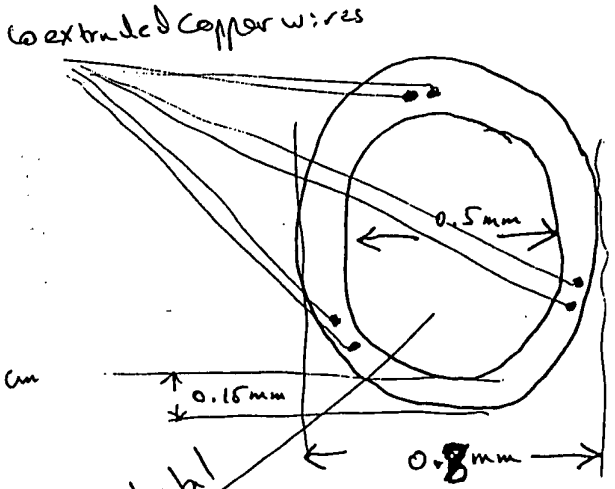


Fig (1)
"pediatric PA catheter diagram"



(Fig 2)
"cross section of catheter"

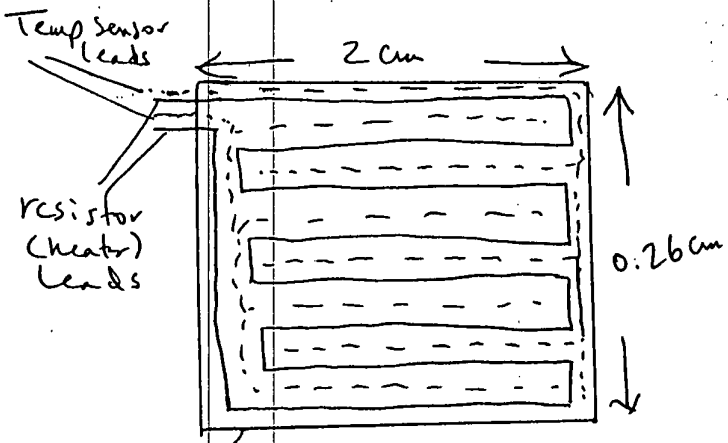


Fig (3)
"Diagram of HTD"

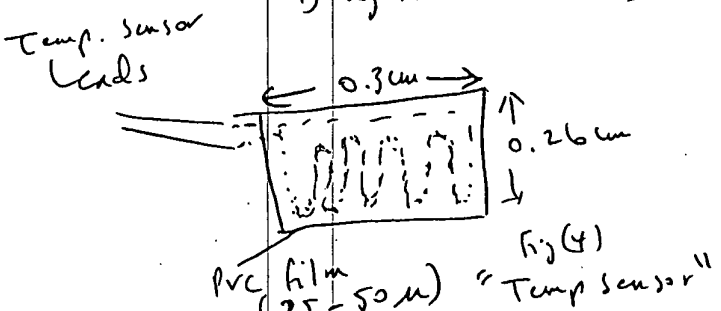


Fig (4)
"Temp sensor"

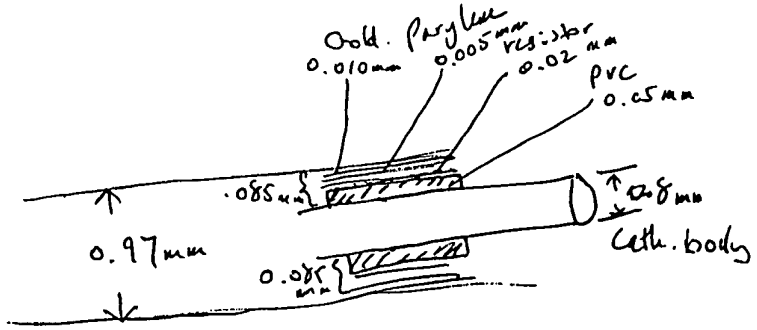


Fig 5

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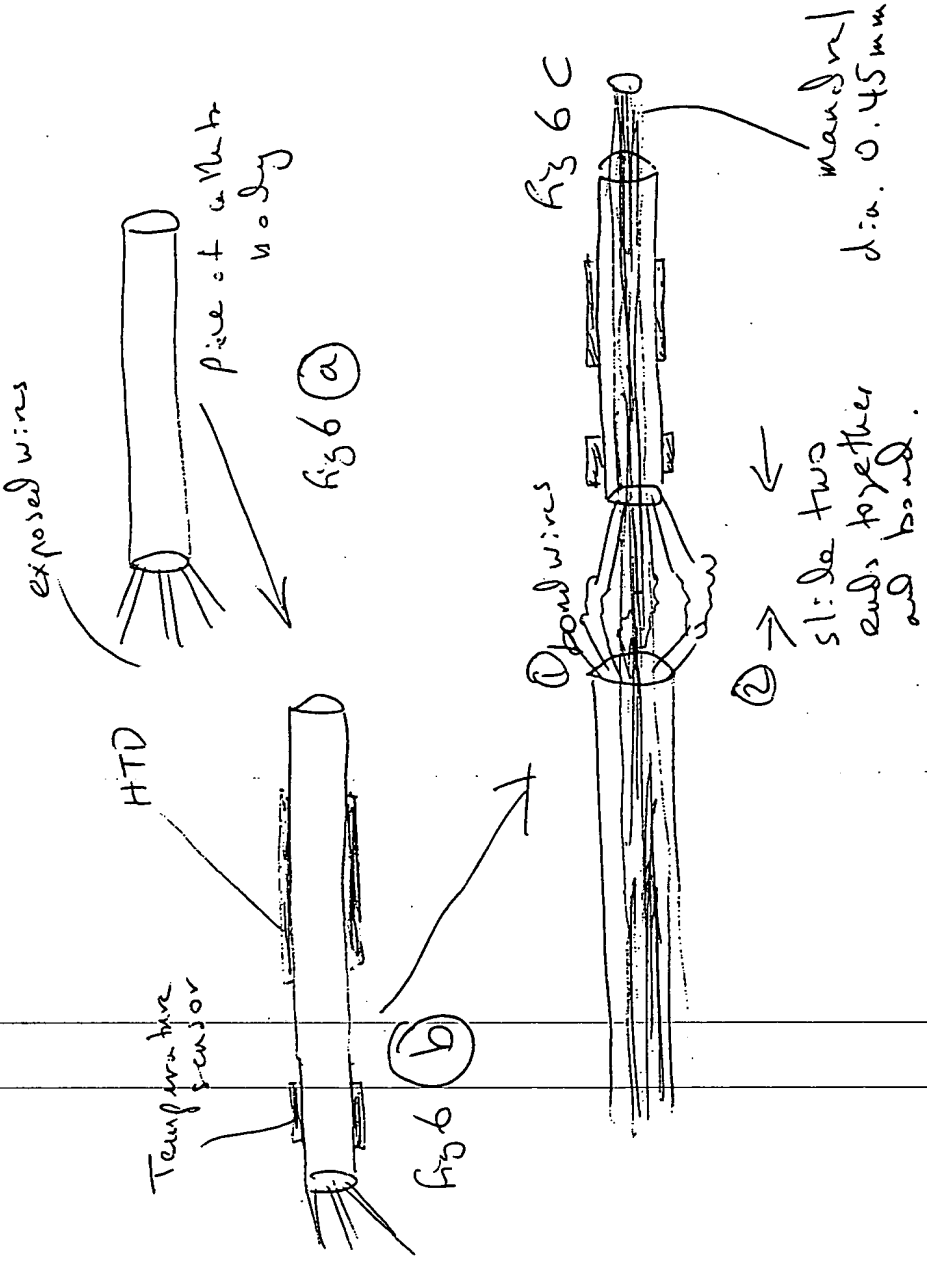
exposed wires
pigtail
Fig 6 (a)
HTD
Temperature sensor
Fig 6 (b)
Fig 6 C
manual
dia. 0.45 mm
① bond wires
② → slide two ends together and bond.

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Form 23/77 : 7.9.00

AGENT : Murgitroyd & Co

Fraser Davies.